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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/355,705	11/05/1999	HUBERT KOSTER	24743-2303US	6820

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EXAMINER	
SISSON, BRADLEY L	

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 06/17/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/355,705	KOSTER ET AL.	
	Examiner	Art Unit	
	Bradley L. Sisson	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-28,44-51 and 53-66* is/are pending in the application.

4a) Of the above claim(s) *48-51* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-28,44-47 and 53-66* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Supplemental Office Action

1. The following is a supplemental Office action to that which was issued 24 April 2002. The period for response has been restarted from the date of mailing of the instant Office action.

Election/Restrictions

2. Applicant's election with traverse of Group I, claims 1-28, 44-47, and 53-56 in Paper No. 18, received 20 February 2002 is acknowledged. The traversal is on the ground(s) that the inventions are so linked as to have unity of invention. Applicant presents argument as to how Groups I and IV; Groups I and V; and Groups I and VI are linked. This is not found persuasive because all of the groups presented, not just some of them, must be so linked as to have unity of invention. To that end, it is noted with particularity that no argument has been presented as to how Group I is so linked with either of Groups II, and III. Absence of argument against the restriction of Groups II and III is taken as tacit approval of same.

The requirement is still deemed proper and is therefore made FINAL.

3. Claims 48-51 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 18.

Priority

4. Applicant's claim for domestic priority under 35 U.S.C. 119(e) is acknowledged. However, the provisional application upon which priority is claimed fails to provide adequate support under 35 U.S.C. 112 for claims 1-28, 44-47, and 53-56 of this application. In order for an application to be entitled to priority of an earlier filing date, the instant application and each and every application in the chain upon which the claim for priority is based, must meet *inter alia* the requirements under 35 USC 112, first paragraph, as it relates to the written description requirement. *Lockwood v. American Airlines Inc.* (Fed. Cir. 1997) 41 USPQ2d 1961, 1966. Claims 1-19, 44-47, and 53-56 are drawn to generic composition claims that encompass virtually any and all biopolymers, and in independent claims, encompass virtually and nucleic acid as well as antibodies. The specification defines the nucleic acid in terms of how it is to function, as it does enzymes, antibodies, etc., yet it does not provide an adequate written description of just what these compounds are. *Enzo Biochem Inc. v. Gen-Probe Inc.* (Fed. Cir. 01-0123; April 2002). Similarly, claims 20-28 are drawn to a method of preparing the composition of claim 1. It is not enough that alternative embodiments may be obvious in light of the disclosure when coupled with what is known in the art, the specification still must adequately describe the invention. *Lockwood.* Accordingly, and in the absence of convincing evidence to the contrary, the claim for priority is not granted.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it

pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1-28, 44-47, and 53-56 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 1-19, 44-47, and 53-56 are drawn to compositions that are comprised of biopolymers which are further defined in dependent claims as being enzymes, nucleic acids (DNA, RNA, analogs or mimetics of DNA or RNA), antibodies, and polypeptides, and that these biopolymers are bound to various supports, be it inorganic, insoluble, magnetic, etc., and that there are various reversible linkages used to bind the biopolymer to said supports. The aspect of defining a biopolymer as being a nucleic acid (including DNA, RNA, analogs or mimetics of DNA or RNA), as well as being a polypeptide, etc., does not satisfy the written description requirement. *Enzo Biochem Inc. v. Gen-Probe Inc.* (Fed. Cir. 01-0123; April 2002). It is not enough that certain undisclosed embodiments may be obvious when the disclosure is coupled with what was known in the art at the time of filing (*Lockwood*), the specification must provide an adequate written description of the invention and for purposes of examination, the invention is what ever is being claimed. *Vas-Cath Inc. v. Mahurkar* 19 USPQ2d 1111 (Fed. Cir. 1991).

7. Claim 6 defines the insoluble support as being selected from a group consisting of a flat surface, a microtiter plate, a comb, and a bead." Claim 7 further defines these supports as being "a silicon wafer, glass plate, metal, plastic, film, and composites thereof with pits or wells" which are defined further as comprising inorganic material selected from the group consisting of

"silica, Controlled Pore Glass (CPG), plastic, metal, cellulose, agarose and dextran cross-linked with epichlorohydrin" (claim 8). Upon review of the disclosure it is noted that there are but four prophetic examples and of which only example 3 (page 15) is most relevant to the claimed invention. Here it is readily seen that a "bead" of some undisclosed type is contemplated for use. The suggestion in a prophetic example does not reasonably suggest that applicant was in possession of the genus of compositions now being claimed. While literal support may be found in the claims for certain embodiments, the specification does not provide an adequate written description of compositions where all or even some of these requisite elements are combined.

1. The specification does not set forth in sufficient detail the method of claims 20-28 whereby one is to produce the compositions encompassed by claim 1. It is noted that the claimed method requires one to utilize various first and second reversible linkages formed through a trityl derivative, chelate complex, a hydrophobic interaction or a photocleavable functionality" (claim 21). Other claims require that an enzymatic process is used to introduce functionalities into nucleic acids and that this enzymatic process is part of a nucleic acid sequencing reaction. A review of the specification, however, fails to find where such methods are described even in the context of a prophetic example. A review of the specification finds the following examples:

a. Example 1 BAP-his_6 Fusion Protein (page 14)

b. Example 2 Dephosphorylation of DNA Fragments with Solid Phase Bound BAP-his_6 (page 15)

c. Example 3 Detection of LCR Products in Microtiter Filter Plates (pages 15-16)

d. Example 4 Sequence Specific Detection of PCR Fragments (page 16)

The examples and guidance provided is found, at best, to only indirectly suggest or make obvious the claimed methods. It is well settled, however, that in order to satisfy the written description requirements of 35 USC 112, first paragraph, that it is not enough that the invention be rendered obvious by the disclosure. In support of this position attention is directed to the decision in *University of California v. Eli Lilly and Co.* 43 USPQ2d at 1405, citing *Lockwood* 41 USPQ2d at 1966:

> Recently we held that a description which renders obvious a claimed invention is not sufficient to satisfy the written description requirement of that invention.

Accordingly, and in the absence of convincing evidence to the contrary, the specification has not been found to provide an adequate written description of the claimed method of producing the claimed compositions

2. Claims 1-28, 44-47, and 53-56 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Aside from providing an adequate written description of the invention, the specification must also enable the use of the invention. As presently worded, the claims encompass a vast multitude of compositions yet the specification does not set forth in sufficient detail just how one is to differentiate between those embodiments that work and those that will not work. The specification teaches at page 1 that the invention is important to the area of reversibly linking biomolecules where it can be used in "DNA sequencing, DNA diagnostics, nucleic acid amplification, Polymerase and Ligase Chain Reactions (PCR, LCR), hybridization experiments and solid phase biochemistry." At page 3 of the disclosure applicant states that

"[b]y combining this reversible concept with other reversible or irreversible linkages, novel biochemical formats including diagnostic assays are possible in which favorable solid phase procedures are coupled with sensitive detection principles." The specification, however, does not teach in sufficient detail just how these multitudinous compositions are to be used in any one of these contemplated methods, much less enable all compositions in all methods. The situation at hand is analogous to that in *Genentech v. Novo Nordisk A/S* 42 USPQ2d 1001. As set forth in the decision of the Court:

> " '[T]o be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation.' *In re Wright* 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993); *see also Amgen Inc. v. Chugai Pharms. Co.*, 927 F. 2d 1200, 1212, 18 USPQ2d 1016, 1026 (Fed Cir. 1991); *In re Fisher*, 427 F. 2d 833, 166 USPQ 18, 24 (CCPA 1970) ('[T]he scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art.').
>
> *****
>
> "Patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable. *See Brenner v. Manson*, 383 U.S. 519, 536, 148 USPQ 689, 696 (1966) (starting, in context of the utility requirement, that 'a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion.') Tossing out the mere germ of an idea does not constitute enabling disclosure. While every aspect of a generic claim certainly need not have been carried out by an inventor, or exemplified in the specification, reasonable detail must be provided in order to enable members of the public to understand and carry out the invention.
> "It is true . . . that a specification need not disclose what is well known in the art. *See, e.g., Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1385, 231 USPQ 81, 94 (Fed. Cir. 1986). However, that general, oft-repeated statement is merely a rule of supplementation, not a substitute for a basic enabling disclosure. It means that the omission of minor details does not cause a specification to fail to meet the enablement requirement. <u>However, when there is no disclosure of any specific starting material or any of the conditions under which a process can be carried out, undue experimentation is required; there is a failure to meet the enablement requirement that cannot be rectified by asserting that all the disclosure related to the process is within the skill of the art.</u> It is the

> specification, not the knowledge of one skill in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement. This specification provides only a starting point, a direction for further research. (Emphasis added)

Accordingly, and in the absence of convincing evidence to the contrary, the specification has not been found to enable the use of the claimed compositions.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.
>
> (f) he did not himself invent the subject matter sought to be patented.

4. The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

5. Claims 1-14 are rejected under 35 U.S.C. 102(e) as being anticipated by Köster (US Patent 6,225,450 B1).

6. Köster, columns 11-12, disclose the reversible immobilization of biopolymers such as nucleic acids to a solid support wherein said biopolymers are reversibly bound to said solid support through a linker means. Column 14, first paragraph, discloses suitable solid supports.

7. Claims 1-14 are rejected under 35 U.S.C. 102(f) because the applicant did not invent the claimed subject matter. The '450 patent to Köster lists but a single inventor yet it describes the invention of claims 1-14.

8. Claims 1-14 are rejected under 35 U.S.C. 102(e) as being anticipated by Rothschild et al. (US Patent 5,948,624).

9. Rothschild et al., Table 4 (column 19), and columns 24-28, disclose the development and wide application of photocleavable biotin (PCB). As disclosed therein, PCB can be used to form conjugates with an extremely wide variety of biopolymers, including polypeptides, nucleic acids, etc. A plethora of applicable solid supports, including insoluble supports are disclosed at column 25. The aspect of having complexes formed off of the conjugated biopolymer whereby one biopolymer is used to bind to yet another biopolymer is disclosed throughout.

Conclusion

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is (703) 308-3978. The examiner can normally be reached on 6:30 a.m. to 5 p.m., Monday through Thursday.

11. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the

organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

12. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

B. L. Sisson

Bradley L. Sisson
Primary Examiner
Art Unit 1634

BLS
June 6, 2002